K 033543

510(k) Summary

As required by 21 CFR 807.92

Date: 2003-10-29

SEP 17 2004

General Company Information

MT MonitorTechnik GmbH u. Co. KG
Maienbaß 27
D-24576 Bad Bramstedt
Germany

Tel: +49 (0) 4192 201753
Fax: +49 (0) 4192 201754
Email: monitortechnik@t-online.de

Name of contact: Friedmund Wieland

Device

Trade name:	Narcotrend Compact 4.0
Common name:	EEG Monitor
Classification:	Product code: OLW, OMC, OLT
	CFR Section: 882.1400 Electroencephalograph
	Classification Panel: Neurology
	Device Class: Class II

Name of legally marketed device for which a claim of substantial equivalence is made

The Narcotrend is of comparable type and is substantially equivalent to the following predicate device:

Name:	A-2000 EEG Monitor with BIS
Manufacture:	Aspect Medical Systems
510(k) No.:	K974496
Date cleared:	1998-02-06

Device description

The Narcotrend is a stand-alone EEG monitor including the following components:

- Preamplifier
- Monitor for data analysis and display
- System lead (connects preamplifier and monitor)
- Patient lead (connects the electrodes with the preamplifier)

The Narcotrend records and processes data of one or two channels of EEG.
The monitor display includes the following:

- Raw EEG
- Power spectrum
- Processed EEG parameters including spectral parameters, EEG stage, and the Narcotrend Index (current values and trend plots)

Intended use

The EEG monitor Narcotrend serves the purpose of registering and displaying EEG signals and thus monitoring the state of the brain.
It was developed specifically for use in operating rooms, intensive care units, and for clinical research.
The Narcotrend includes the Narcotrend Index, a processed EEG parameter which may be used as an aid in monitoring the effects of certain anesthetic agents.

Summary of technological characteristics compared to predicate device

The Narcotrend and the predicate device are similar in the following ways:

- Both devices record and display the EEG.
- Both monitors provide processed EEG parameters including a numerical EEG index which serves as an aid in assessing the hypnotic effects of certain anesthetic agents.
- Both devices conduct self-tests and electrode checks (automatic and manual).
- Both devices have capabilities for marking events and reviewing stored data.
- Both devices have capabilities for printer support and data transfer via RS232 serial port.
- Both systems have two main components, a monitor and a preamplifier.

The Narcotrend and the predicate device are different in the following ways:

- The Narcotrend is operated via touch screen while the predicate device is operated via keys.
- The Narcotrend includes a high resolution color monitor while the predicate device has a monochrome monitor.

- By default, the Narcotrend uses standard single-use ECG electrodes while the predicate device uses specially designed EEG sensors placed on the forehead.
- The Narcotrend can record and display two channels of EEG while the predicate device uses one channel of EEG.

Summary of nonclinical testing for the device

The Narcotrend complies with the safety standards below and is therefore safe and effective for the intended use. The device has been thoroughly tested including electrical safety, electromagnetic compatibility, mechanical and environmental tolerance, software validation and verification of specifications. Verification with the following mandatory and voluntary standards and guidelines has been made:

- IEC 60601-1, Medical electrical equipment - Part 1: General requirements for safety
- IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-4, Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems
- IEC 60601-2-26, Medical electrical equipment - Part 2: Particular requirements for the safety of electroencephalographs
- Electroencephalograph Devices, Guidance for 510(k) Content, Draft Document, Version 1.0, November 3,1997
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 29, 1998

Summary of clinical testing for the device

Results of randomized controlled clinical trials demonstrate equal effectiveness of the Narcotrend and the predicate device regarding the assessment of hypnotic drug effects during general anesthesia.

Conclusion

The summary above shows that there are no new questions of safety and effectiveness for the Narcotrend as compared to the predicate device. We believe that the submitted device is substantially equivalent to the predicate device, and is safe for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Friedmund Wieland
President
MT MonitorTechnik GmbH u. Co. KG
Maienbas 27
D-24576 Bad Bramstedt
Germany

APR - 9 2012

Re: K033543
Trade/Device Name: Narcotrend Model Compact 4.0
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLW, OMC, OLT
Dated (Date on orig SE ltr): June 18, 2004
Received (Date on orig SE ltr): June 21, 2004

Dear Mr. Wieland:

This letter corrects our substantially equivalent letter of September 17, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 033543

Device Name: Narcotrend Compact 4.0

Indications For Use:

The EEG monitor Narcotrend serves the purpose of registering and displaying EEG signals and thus monitoring the state of the brain.

It was developed specifically for use in operating rooms, intensive care units and for clinical research.

The Narcotrend includes the Narcotrend Index, a processed EEG parameter which may be used as an aid in monitoring the effects of certain anesthetic agents.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use ✓ AND/OR Over The Counter use ——

Miriam C. Provost (Optional Format 3-10-98)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K033543